

APPENDIX C

**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS**

IN RE: COLUMBIA UNIVERSITY)	MDL NO. 1592
PATENT LITIGATION)	
)	
IMMUNEX CORPORATION, a)	CIVIL ACTION NO.: 04-10740-MLW
Washington Corporation and)	
AMGEN INC., a Delaware Corporation,)	C. D. Cal. No. CV 03-4349 MRP (CWx)
)	
Plaintiffs,)	Judge Mark L. Wolf
)	
vs.)	
THE TRUSTEES OF COLUMBIA)	
UNIVERSITY in the City of New York, a)	
New York Corporation,)	
)	
Defendant.)	
)	
AND RELATED COUNTERCLAIM.)	
)	

**AMGEN INC.'S AND IMMUNEX CORPORATION'S REPLY MEMORANDUM IN
SUPPORT OF THEIR MOTION TO SUPPLEMENT AND AMEND COMPLAINT**

**I. THE LIBERAL RULES OF PLEADING APPLY ESPECIALLY WHERE -- AS IN
THIS CASE -- CLAIMS SURVIVE A MOTION TO DISMISS**

Columbia does not dispute that the grounds for denial of a motion to amend are futility, bad faith, undue delay, a dilatory motive, or prejudice. Nor does Columbia argue that any of those grounds is present here. Instead, Columbia argues that Amgen's claims for relief have been dismissed -- a theory that is both inaccurate in fact and in law.

Subject matter jurisdiction still exists for Amgen's First and Seventh Claims, which request a declaration of certain rights and obligations under the parties' license agreements,

including royalty obligations based on sales after expiration of the original Axel patents. Columbia itself admits to a dispute over payment of royalties on post-expiration sales. Columbia's Brief in Opposition to Motion to Amend and Supplement Complaint ("Col. Opp.") at 3.

Nonetheless, in asserting that Amgen's contract claims must be dismissed while its own counterpart counterclaims survive, Columbia erroneously frames Amgen's First and Seventh Claims for Relief as limited to "declaratory judgment regarding the '275 patent," Col. Opp. at 5. Columbia invents such a limitation in the Second Amended Complaint ("SAC"), whose allegations encompass the royalties allegedly owed under the original Axel patents. For example, ¶ 60 in the First Claim of the SAC alleges that "[a]n actual controversy has arisen and now exists between Plaintiffs, on the one hand, and Columbia, on the other hand, concerning whether, as Columbia contends, Plaintiffs are breaching the License Agreement by non-payment of royalties for periods after August 16, 2000"—not limited to periods after September 2002, when the '275 patent issued. SAC at ¶ 60. Paragraph 58, incorporated by reference in ¶ 59 of the First Claim, specifically refers to Columbia's "demand upon Amgen and Immunex in the name of the License Agreement for the payment of royalties for sales occurring after August 16, 2000, even though the '216, '665 and '017 patents had expired." These allegations for declaratory relief encompass a determination of what, if any, royalties are owed for sales occurring after August 16, 2000, whether based on Columbia's demand for royalties on post-expiration sales which allegedly fall under the original Axel patents, or on "*inter alia*, claims in pending patent applications." SAC at ¶¶ 61-62.

Columbia similarly misreads and ignores allegations in Amgen's Seventh Claim for Relief in arguing that the Seventh Claim is limited to "declaratory judgment regarding the '275

patent.” Columbia ignores not only the broad title of the Seventh Claim, “Amgen and Immunex Have No Contractual Royalty Obligations Based on Columbia’s Failure to Perform Condition,” but also the absence of any statement in ¶¶ 88-92 that would limit the disputed royalty obligations to those under only the ‘275 patent. Instead, ¶¶ 89-92 of the Seventh Claim refer generally to Columbia’s repressive practices in derogation of Amgen’s rights under the License Agreement – not to royalties owed under any one Axel patent.¹ In addition, the Seventh Claim incorporates by reference ¶ 58’s discussion of Columbia’s demand for post-expiration royalties. Thus, Columbia’s inartful attempts to paint the First and Seventh Claims as “pertain[ing] solely to Amgen’s obligations to pay royalties based on the ‘275 patent . . . ,” Col. Opp. at 6, have no colorable basis.²

Since Amgen’s First and Seventh claims of its SAC survive Columbia’s Motion to Dismiss, Columbia’s argument that leave to amend should be denied due to successful resolution of a motion to dismiss is inapplicable. Columbia has failed to cite any court’s refusal to permit amendment to add allegations based on newly discovered facts and events, where a motion to

¹ That Columbia’s mischaracterization of Amgen’s First and Seventh Claims is nothing more than its latest stratagem to prevent Amgen from obtaining declaratory relief is evidenced by comparing the general allegations in Columbia’s Counterclaims with its description of the “Background Facts” in its Opposition, Col. Opp. at 3. Although Columbia’s Counterclaims allege only generally that Amgen and Immunex have breached their respective License Agreements by “failing to pay royalties on sales of licensed products . . . ,” Columbia’s opposition elaborates on its Counterclaims by asserting that Amgen owes royalties under the license agreement for “licensed product that it manufactured *during the term of the original Axel patents*,” Col. Opp. at 3. Even though Columbia must therefore interpret its own generally stated Counterclaims to cover breach of contract for alleged failure to pay royalties under both the ‘275 patent and the original Axel patents, Columbia inexplicably reads Amgen’s First and Seventh Claims for declarations of no royalties owed as limited to royalties owed under the ‘275 patent. Columbia cannot have it both ways—it cannot argue that its Counterclaims present the issue of whether Amgen owes royalties under the prior issued Axel patents when its Counterclaims are nothing more than generally stated counterparts to Amgen’s First and Seventh Claims.

² Columbia’s argument that Amgen failed to properly assert that the First and Seventh Claims survive the Motion to Dismiss is unsupported. See Opp. Br. at 5-7. Amgen’s Opposition to Columbia’s Emergency Motion to Dismiss (“Amgen’s Opposition”) specifically cited Amgen’s First Claim as one that would survive regardless of the outcome of the Emergency Motion. Amgen’s Opp. at 14. Amgen’s Opposition further stated that “Amgen’s claim for declaratory relief regarding contract rights remains,” *id.* at 2, and discussed significant common questions that would remain in the MDL, including “Columbia’s repressive practices that excuse contractual performance by plaintiffs,” *id.* at 14-15—the practices at issue in Amgen’s Seventh Claim.

dismiss was successful for only some of the claims at issue.³ When only some claims are dismissed on a motion, no dispositive ruling weighs against amendment and the liberal standards for amending and supplementing pleadings apply. *See In re One Meridian Plaza Fire Litigation*, 1993 WL 308726 (E.D. Pa. 1993) (granting motion for leave to file Second Amended Complaint despite order granting in part and denying in part defendant's motion to dismiss); *see also Bush v. United Parcel Service*, 2000 WL 1780353 (N.D. Ill. 2000) (holding that dismissal of complaint did not dismiss entire action and granting plaintiff's motion to file a third amended complaint with respect to amendments which stated a claim despite the court's dismissal of the Second Amended Complaint for failure to state a claim). Amgen should therefore be given leave to amend and supplement its claims to include allegations based on newly discovered information and later transpired events.

Although Judge Pfaelzer's January 27, 2004 Order denying Columbia's motion to dismiss Amgen's Seventh Claim stated that "[f]urther leave to amend will not be granted," that Order was made in the context of her intention that discovery and pre-trial would be very abbreviated leading to trial in December 2004,⁴ and did not preclude amendment based on later discovered facts without further analysis or justification. The Supreme Court has held that "outright refusal to grant the leave [to amend] without any justifying reason appearing for the denial" is an abuse of discretion "inconsistent with the spirit of the Federal Rules." *Foman v. Davis*, 371 U.S. 172, 1982, 83 S. Ct. 227, 9 L. Ed. 2d 222 (1962). Furthermore, Judge Pfaelzer's

³ *In Re Recombinant DNA Technology Patent and Contract Litigation*, cited by Columbia, actually supports amendment here. That court granted Genentech's motion to file a Second Amended Complaint "to include recently discovered conduct" which could not have been included in the Amended Complaint. *In Re Recombinant DNA Tech. Patent and Contract Litig.*, 874 F. Supp. 904, 916 (S.D. Ind. 1994). That court also granted leave to amend to state a new legal basis based on facts already pleaded: "[T]o the extent that Genentech seeks to amend to add a common law unfair competition claim based on conduct already pleaded, we believe such amendment is proper." *Id.* at 919.

ruling was superseded during the hearing on Columbia's Motion to Stay, when the Court denied Columbia's request to set a deadline for amendment of pleadings, and indicated that amendments to the pleadings were to be made after the obviousness-type double-patenting portion of the case was completed, in January. See Excerpt of June 22, 2004 Hearing Transcript at 194:23-197:24, attached as Exhibit A.

Here, the just disposition of this case requires that Amgen be permitted to amend and supplement its pleadings since the allegations Amgen seeks to add are based on information newly discovered, and conduct occurring after Amgen's December 10, 2003 filing of the SAC, as demonstrated by Amgen at pages 2-3 of its opening Memorandum.

II. BEFORE ADDRESSING WHETHER GOOD CAUSE EXISTS FOR REMAND OF THIS ACTION, THE CLAIMS AND FACTUAL DISPUTES AT ISSUE IN EACH OF THE CONSOLIDATED CASES SHOULD BE DETERMINED

Columbia argues that the decision on whether to permit amendment of the pleadings should be deferred until after the Court rules on whether to suggest to the J.P.M.L. that it remand this action to the transferor court. This is the reverse of logical order. Under Columbia's proposal, in deciding whether good cause had been demonstrated for remand, the J.P.M.L. could only consider the common facts pleaded but not those which will be pleaded by amendments. If the cases are remanded and amendment is subsequently granted, the J.P.M.L. will again have to decide whether consolidation is appropriate – this time in light of the amended pleadings. Clearly, this is an inefficient use of judicial resources.

Columbia's argument that "the reason for consolidation was that each lawsuit presented common questions relating to the validity and enforceability of the '275 patent" (Col. Opp. at 4)

⁴ Her Civil Minutes of February 18, 2004 set a discovery cutoff of August 27, 2004 and a trial date of December 7, 2004.

directly contradicts its reliance upon common facts regarding the license agreements in urging the J.P.M.L. to send these cases to one court:

[C]lose similarity between the complaints carries over to allegations relating to Columbia's obligations under a letter agreement with the National Institute of Health ("NIH") not to engage in "repressive royalty practices." . . . Moreover, every Plaintiff serving discovery upon Columbia has requested the production of documents on this issue . . .

Columbia University's Reply Brief in Support of Motion to Transfer under Section 1407, Jan. 19, 2004, p. 5.

Moreover, as Amgen demonstrated in its Memorandum at pages 11-12, efficiency requires consideration of the proposed pleadings when determining whether good cause has been shown to remand. Since Amgen filed its Motion to Amend, additional filings have further delineated the common facts in these cases weighing against remand. The Amgen Affiliates filed a new pleading placing Columbia's repressive practices at issue, *see Amgen Mfg. v. Trs. of Columbia Univ.*, Case No. 04-12626 MLW, Complaint, at ¶¶ 102-05, just as in Amgen's Seventh Claim and in Biogen-Idec's complaint, *see Biogen Idec Inc. v. Trs. of Columbia Univ.*, Case No. 04-12009 MLW, Complaint, at ¶ 82. In addition, Biogen Idec filed an amended pleading alleging that Columbia breached the most favored nation provision of its license agreement—a breach that is also alleged in Amgen's proposed amendment to its First Claim for Relief. *See Biogen Idec Inc. v. Trs. of Columbia Univ.*, Case No. 04-12009 MLW, Amended Complaint, at ¶¶ 72, 83-84; *see also* Third Amended Complaint at ¶ 79. Finally, both Biogen Idec and the Amgen Affiliates have alleged the invalidity and unenforceability of the '275 patent, presenting legal and technological issues with which this Court is well-versed. *See, e.g., Biogen Idec Complaint* at ¶¶ 94-97 (invalidity); ¶¶ 98-100 (laches); ¶¶ 101-128 (inequitable conduct); *Amgen Mfg. Complaint* at ¶¶ 76-81 (invalidity); ¶¶ 89-93 (laches); ¶¶ 82-88 (inequitable conduct).

Efficiency dictates that each of these amendments be considered in determining whether Columbia has demonstrated good cause to remand.

CONCLUSION

For the above reasons and those set forth in Amgen's Memorandum in support of its Motion to Amend, Amgen respectfully requests that the Court grant Amgen's Motion to Amend the Complaint.

Dated: January 4, 2005

Respectfully submitted,

IMMUNEX CORPORATION, a Washington Corporation and AMGEN INC., a Delaware Corporation

By their attorneys,

/s/ Eileen M. Herlihy

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EXHIBIT A

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

BIOGEN, INC., ET AL) CA 03-11329
v.) Boston, MA
COLUMBIA UNIVERSITY, ET AL) June 22, 2004
)
)

BEFORE THE HONORABLE MARK L. WOLF
UNITED STATES DISTRICT JUDGE

APPEARANCES:

(As previously noted.)

JUDITH A. TWOMEY, RPR
Official Court Reporter
One Courthouse Way
Courtroom 10-Room 5200
Boston, MA 02210
(617) 946-2577

1 tape.

2 THE COURT: But Biogen has already paid for it
3 once. First, they did it with power point, and I had a
4 book, and so I had each slide and I could write on it.
5 And then they had something that was animated the second
6 time. But it exists, and it's the same technology,
7 right? I mean, it's the same process.

8 All right, we need to build in a date for the
9 tutorial, which should be after November 1, right? But
10 not too far after it. How about the 5th. Is that okay?

11 MS. BEN-AMI: On your calendar, I just wanted to
12 remind your Honor that I am at trial during the time
13 period --

14 THE COURT: But you've got to do the following.
15 You've, first of all, got to get somebody else with you.
16 I hope some of those 40 people were with you.

17 MS. BEN-AMI: I have one.

18 THE COURT: Get two more. And that's one. And
19 you all think you're going to win on summary judgment.

20 MS. BEN-AMI: I agree with that.

21 THE COURT: We'll cross that bridge when we come
22 to it.

23 MR. GINDLER: There's one other date I think we
24 should set now, which is a last day by which pleadings
25 should be amended, because we have counterclaims that we

1 would like to assert, both breach of contract, which will
2 live no matter what, and infringement, but won't be done
3 now, but I think we should at least --

4 THE COURT: Why?

5 MR. GINDLER: Because I think that it's only
6 fair to just close the pleadings and to put our claims on
7 the table, and the infringement claims could be
8 terminated if we lose on double patenting. The breach of
9 contract claims will not, though, because those simply
10 applied during the period before anyone sued. And so
11 those will be royalty claims.

12 We're not proposing to do anything with the
13 claims. We just think they should be on the table.

14 THE COURT: You have so much to do. Why do
15 that? I don't know. What do you think? Maybe I'm
16 missing something.

17 MR. WARE: Your Honor, at least in the case of
18 Biogen and Genzyme, there is a stand-still agreement that
19 infringement claims won't be asserted. So it's obviously
20 not germane to our case. I don't really see why it's
21 necessary.

22 With respect to contract counterclaims, I think
23 we would want the opportunity to oppose the time to add
24 such claims into the case at this point, which come a
25 year after we sought an declaration of -- that no

1 royalties were owed. So we would certainly at least want
2 the opportunity to oppose adding such claims into the
3 case at this point. But I don't see why it's necessary.

4 THE COURT: You'd claim they're futile or
5 something?

6 MR. WARE: No, I'd claim there are no admitted
7 counterclaims. We specifically asserted that we did not
8 owe royalties.

9 MR. GINDLER: We tried to keep activity down to
10 a low buzz before we got before a single court. It took
11 us a long time to get here. We started this process in
12 October of last year, with opposition by every plaintiff,
13 and we finally got to one court. That's good. So we
14 want to be as in a position so that if, for example, the
15 court were to rule against us on double patenting, okay,
16 that takes a lot out of the case. What's left? Well, we
17 should know what's left. And so --

18 THE COURT: Frankly, if I rule against you or
19 the jury finds against you on double patenting, I hope
20 you're all going to sit down in a businesslike way and
21 see if you can work it out. That's the purpose of all of
22 this.

23 MR. GINDLER: But I do think it makes sense to
24 just put those on the pleadings.

25 THE COURT: Why not put them on the pleadings in

1 the beginning of January?

2 MR. GINDLER: We could do it then.

3 THE COURT: I'm trying to get you off for the
4 4th of July.

5 MR. GINDLER: You succeeded.

6 THE COURT: Did Mr. Barsky show your wife the
7 transcript? Some other judge will probably foul it up.

8 MR. BARSKY: I'd point out that there are some
9 counterclaims, contract counterclaims in the consolidated
10 cases already. For example, the case I'm counsel on,
11 Amgen. There are those counterclaims already.

12 THE COURT: I'm really just trying to get this
13 focused. And maybe I've miscalculated. But I just think
14 this is -- you know, the validity of this patent is very
15 important to all of you, and Mr. Goldberger was telling
16 me Malcolm Baldrige, Secretary of Commerce, has
17 subsequently said, you know, he could manage adversity,
18 he couldn't manage uncertainty. And your clients can
19 manage adversity, but this is really important, I think,
20 and these products are very important. They're not
21 widgets. They're very important to human health.

22 MR. GINDLER: If you prefer to have the date in
23 January, it's okay with us.

24 THE COURT: Yeah. Just try to keep our eye on
25 this ball and, you know, they think they've got a great

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CERTIFICATE

I, JUDITH A. TWOMEY, RPR, Official Court Reporter for the United States District Court, District of Massachusetts, do hereby certify that the foregoing transcript, pages 1 through 200 inclusive, was taken by me stenographically and thereafter by me reduced to transcription and is a true record of the proceedings in the above-entitled matter to the best of my ability.

JUDITH A. TWOMEY, RPR
Official Court Reporter